K083872

Medacta International

510(k) Summary

JAN 15 2009

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Date Prepared: Dec. 11, 2008

DEVICE INFORMATION

Trade/Proprietary Name: iMNS Medacta Navigation System
Common/Classification Name:
21 CFR 882.4560
Class II
Device Product Code: HAW

Predicate Device: K061362 PiGalileo™ Total Knee Replacement (TKR) System

Product Description:
The iMNS Medacta Navigation System is a device for computer aided navigation of surgical instruments used in total knee replacement surgery. The system works on the common principle of stereotaxic technology in which passive markers are securely mounted on the patient's bones and an infrared camera is used to monitor the spatial location of those markers. This information is used to locate the anatomical landmarks such as centers of rotation of the femur head, knee and ankle intraoperatively. These measurements are displayed on a computer screen in real time. The

instruments are then outfitted with the passive markers to improve the positioning of the cutting guides. The information from the system with the "navigated" instruments assists the surgeon in optimally conducting the bone resections and positioning of the orthopedic surgical implants. The surgeon maintains control of the surgery and makes any decisions required with regard to bone resections and implant positioning but the iMNS Medacta Navigation System provides real time support and information throughout the surgery.

The iMNS Medacta Navigation System consists of the following key components:

- An acquisition system composed of two infrared cameras equipped with infrared light emitting diodes (LED) to track the position of the passive markers,
- A computer running the proprietary Medacta software and a monitor,
- Interface devices of a keyboard, foot pedal and optional mouse to control the system, and
- Manual reusable surgical instruments.

The software application called Evolis Global Femur First is designed to work with Medacta's Evolis Total Knee System, cleared under K081023. The manual reusable surgical instruments include instruments specifically designed for navigated surgery and other standard surgical instruments needed to conduct total knee replacement.

Indications for Use:
The iMNS Medacta Navigation System is intended to be used to support the surgeon during specific orthopedic surgical procedures by providing information on bone resections, instrument and implant positioning during joint replacement.

The iMNS Medacta Navigation System provides computer assistance to the surgeon based on anatomical landmarks and other specific data obtained intra-operatively that are used to place surgical instruments.

Examples of some surgical procedures include but are not limited to:

Total Knee Replacement
Minimally Invasive Total Knee Replacement

Performance Testing
No performance standards applicable to this device have been adopted under Section 514 of the Food, Drug and Cosmetic Act. Performance testing of the iMNS Medacta Navigation System was conducted in accordance with design controls, international standards and FDA guidance documents.

The iMNS Medacta Navigation System was tested as part of design verification to written protocols with pre-defined acceptance criteria. The

testing met all acceptance criteria. Design validation was conducted on the iMNS Medacta Navigation System in a simulated user setting by a surgeon and demonstrated that the system meets user needs and intended uses.

Comparison to Predicate Device

The iMNS Medacta Navigation System is similar to or identical to the predicate device, the PiGalileo™ Total Knee Replacement System in the following aspects: Intended Use/Indications for Use, design features, operating principle, type of optical tracking system, graphical user interface, control switch, passive locators, navigated surgery process, sterility, and biocompatibility aspects.

The main differences between the iMNS Medacta Navigation System and the predicate device are the type of computer, the lack of a motorized cutting guide, and the model of the optical tracking system. None of these differences raise any new issues of safety or effectiveness.

Conclusion:

The data and information provided in this submission support the conclusion that the iMNS Medacta Navigation System is substantially equivalent to its predicate device, Plus Orthopedics PiGalileo™ Total Knee Replacement System with respect to indications for use, operating principle, and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medacta International, SA
% Underwriters Laboratories, Inc.
Ms. Casey Conry
1285 Walt Whitman Road
Melville, New York 11747

JAN 15 2009

Re: K083872
Trade/Device Name: iMNS Medacta Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: OLO, HAW
Dated: December 19, 2008
Received: December 29, 2008

Dear Ms. Conry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K083872

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083872